Appln No.: 09/557,955
Amendment Dated: August 2, 2003
Reply to Office Action of March 27, 2003

REMARKS/ARGUMENTS

This is in response to the Office Action mailed March 27, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request an extension of time sufficient to make this paper timely and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

The Examiner has indicated that claims 12-20 are allowed.

Claims 2-11 stand rejected under 35 USC 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection. The Examiner states that it is unclear whether the claim is directed to an assay device, a process of assaying, or the particulate reagent. Applicants do not understood that basis for this statement since claim 9 plainly beings with the phrase "In an assay device..." and all of the dependent claims refer to "an assay device."

The Examiner also states that the claim is confusing because "the prior claim required binding of the labeled reagent in a detection and control zone. Now the claim states that the non-specific protein which can participate." Applicants submit that the claim stands on its own, and should not be judged based on a prior claim. More importantly, however, the claim is directed to an assay device as it would be provided for use in testing. At this time, the labelled reagent has not yet been carried into the detection and control zones (an event which occurs when the device is used) and therefore the control reaction has not occurred, it is a reaction that **can occur** because of the binding specificity. To clarify this point, Applicants have amended claim 9.

The Examiner's statement that claim 9 does not comply with 37 CFR § 1.75(e) is also not understood. The claim clearly includes a preamble portions, a reference to an improvement, and a section of elements, steps and/or relationships that are set forth as the new or improved portion.

The Examiner's statements concerning claims 5-7 appears to be based on the application of a standard to Jepson claims that is different from other claim formats, including a requirement that the portion of a dependent claim which is admitted prior art must be clearly delineated. Applicants are not aware of any reason why the dependent claims in this application are required to meet any standard other than that of allowing a person skilled in the art to understand the scope of the claim, when read in light of the specification. Furthermore, Applicants do not agree with the Examiner's implied suggestion that the level of skill in the art is so low as to preclude understanding of the claims as they are now presented. Nevertheless, to facilitate allowance amendments in line with the Examiner's comments have been made.

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With respect to claim 8, the Examiner asserts that antecedent basis is still lacking, but does not say why. Claim 8 read "An assay device according to claim 7, wherein said ratio is about 3:1." Claim 7 refers to a ratio, which is at least 2:1. No ambiguity is seen in these claims. One simply takes claim 7 and replaces the words "at least 2:1" with "about 3:1" to arrive at claim 8.

On the merits, the Examiner has applied US Patent No. 5,662871 of May as anticipating the claims 5, 9, 10 and 11. Claim 9 has been amended to make it clear that the labeled reagent is captured in the control zone as a result of binding of the non-specific protein. The BSA in May serves solely as a blocking agent, and is not involved in any binding reaction. Thus, claim 9, as amended, as well as claims 5, 10 and 11 which are dependent thereon are not anticipated by May. Additional differences which exist between claims 5, 10 and 11 and the cited art will not be further addressed.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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